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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,198	03/27/2001	Jane Ye	CL001188	9081

7590 01/14/2003
CELERA GENOMICS CORPORATION
45 West Gude Dr. C2-4#20
Rockville, MD 20850

EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,198

Applicant(s)

YE ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,8,9 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8,9,25,26 and 28 is/are allowed.
- 6) ☒ Claim(s) 4,24,27 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

1. The election with traverse filed October 7, 2002 in Paper No. 8 is acknowledged and has been entered.
2. The amendment filed October 7, 2002 in Paper No. 8 is acknowledged and has been entered. Claims 1-3, 5-7, and 10-23 have been canceled. Claims 4 and 8 have been amended. Claims 24-29 have been added.
3. Claims 4, 8, 9, and 24-29 are pending in the application and are currently under prosecution.

Election/Restrictions

4. Upon consideration of Applicants' grounds of traversal of the restriction set forth in the Office action mailed August 7, 2002 (Paper No. 5), the inventions of groups III and IV are rejoined. As Applicants have remarked in Paper No. 8, MPEP § 2434 states, "[n]ucleotide sequences encoding the same protein are not considered to be independent and distinct and will continue to be examined together". Furthermore, the search required for examination of claims drawn to a nucleic acid molecule encoding the polypeptide of SEQ ID NO: 2 is the same as the search required to examine claims drawn to a nucleic acid molecule comprising SEQ ID NO: 1 or SEQ ID NO: 3. Accordingly, searching the inventions of groups III and IV should not constitute a serious burden and therefore it would be improper to maintain the requirement that Applicants elect only one or the other of the inventions of groups III and IV. For the same reasons, the inventions of groups V and VI and the inventions of groups VIII and IX are also rejoined, although it is noted that claims drawn to non-elected inventions have been canceled. Otherwise the restriction requirement is proper and therefore made final.

Lack of Compliance with the Requirements of 37 CFR §§ 1.821-1.825

5. The communication filed July 17, 2002 in Paper No. 4 is not fully responsive to the Office communication mailed June 19, 2002 (Paper No. 3) for the reasons set forth on the attached Notice To Comply With The Sequence Rules and the same form that was attached to Paper No. 5. Applicants must comply with the requirements of the sequence rules (37 CFR §§ 1.821 - 1.825) before the application can be further examined under 35 U.S.C. §§ 131 and 132.

Since the reply appears to be *bona fide* attempt to comply with the requirements of the sequence rules (37 CFR §§ 1.821 - 1.825), Applicants are given the same period time within which to reply to this Office action to correct the deficiency so as to comply with the sequence rules (37 CFR §§ 1.821 - 1.825) in order to avoid abandonment of the application under 37 CFR § 1.821(g).

Specification

6. The disclosure is objected to because the disclosure refers to embedded hyperlinks and/or other forms of browser-executable code, which are impermissible and require deletion. See page 13, for example.

The attempt to incorporate essential or non-essential subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP § 608.01(p), paragraph I regarding incorporation by reference.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 24, 27, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is vague and indefinite because it cannot be ascertained which polypeptide expressed by the host cell of claim 9 is to be produced by the process that

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is regarded as Applicants' invention. Quite literally, thousands of polypeptides are likely to be produced by the host cell of claim 9. Therefore the subject matter that is regarded as Applicants' invention is not particularly or distinctly claimed. Amending claim 24 to recite, for example, "a process for producing a polypeptide comprising the amino acid sequence of SEQ ID NO: 2" can obviate this ground of rejection.

Claim 24 is also vague and indefinite because the claim does not recite a positive correlation step that clearly relates back to the preamble of the claim. Therefore, it is unclear whether each of the steps that Applicants regard as essential to achievement of the objective stated in the preamble of the claim are recited in the body of the claim. Accordingly, one skilled in the art would not be reasonably apprised of the metes and bounds of the invention. Amending claim 24 to recite, for example, "thereby producing said polypeptide" at the end of the last line of the claim can obviate this ground of rejection.

Claims 27 and 29 are indefinite because claim 27 recites the limitation "wherein said vector is selected from the group consisting of a plasmid, a virus, and a bacteriophage". The recitation of this limitation renders the claim indefinite because the vector of claim 8 is "[a] nucleic acid vector"; and while a plasmid is a nucleic acid vector, neither a virus nor a bacteriophage is a nucleic acid vector. Because of this lack of clarity and particularity, one skilled in the art would not be reasonably apprised of the metes and bounds of the invention. Amending claim 8, for example, to delete "nucleic acid" before "vector" can obviate this ground of rejection.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim *Biochemicals*, 1994 Catalog (No. 1034 731/1006 924), page 93.

Boehringer Mannheim teaches a kit comprising random primers that encompass all possible 6-nucleotide sequences. The kit will comprise an isolated nucleic acid molecule consisting of a polynucleotide sequence that is completely complementary to a polynucleotide sequence that encodes the amino acid sequence set forth in SEQ ID NO: 2, namely the polynucleotide sequence set forth in SEQ ID NO: 1.

Conclusion

11. Claims 4, 24, 27, and 29 are rejected. Claims 8, 9, 25, 26, and 28 can be allowed, but are subject to an interference search.

12. The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure. WO 2002/18424-A teaches the polynucleotide sequence of an isolated nucleic acid molecule that encodes an amino acid sequence that is 100% identical to the amino acid sequence set forth in SEQ ID NO: 2. WO 2001/54733-A1 teaches the amino acid sequence of a polypeptide that comprises the amino acid sequence set forth in SEQ ID NO: 2.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.

Examiner

Art Unit 1642

slr

January 12, 2003



ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notic to Comply

Application No.

09/817,198

Examiner

Stephen L. Rawlings, Ph.D.

Applicant(s)

YE ET AL.

Art Unit

1642

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: A detailed explanation of the reasons this application fails to comply with the requirements was set forth on this form as part of the Office communication mailed June 19, 2002 (Paper No. 3). Applicants are directed to submit substitute copies of the sequence listing and the statement, as indicated below, if necessary to place this application in compliance with the requirements.

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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